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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,496	02/07/2001	David M. Lubman	UM-06106	8813

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EXAMINER	
MAHATAN, CHANNING	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/778,496	LUBMAN ET AL.	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-24 and 26-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-24 and 26-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 23 August 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-6, 8-24, and 26-37. Claims 7 and 25 have been cancelled.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-6, 8-20, 22-24, and 26-33 under 35 U.S.C. § 103(a) as being unpatentable over Chong et al. (Rapid Screening of Protein Profiles of Human Breast Cancer Cell Lines Using Non-porous Reversed-phase High Performance Liquid Chromatography Separation with Matrix-assisted Laser Desorption/Ionization Time-of-flight Mass Spectral Analysis. Rapid Communications in Mass Spectrometry, 1999, Volume 13, page 1808-1812) taken in view of Richmond et al. (High-throughput flow injection analysis-mass spectrometry with network delivery of colour rendered results: the characterisation of liquid chromatography

fractions, Journal of Chromatography. 1999, Volume 835, pages 29-39) are maintained for reasons of record.

Applicants argue: 1) Richmond et al. fails to teach that the display methods applied to chemical samples can be used in the display of protein samples, let alone multiple protein samples; 2) neither Chong et al. nor Richmond et al., alone or in combination, teach the claim element of a protein profile map that displays protein abundance and mass of a separated protein sample; and 3) neither Chong et al. nor Richmond et al., alone or in combination, provide a teaching of a side by side display showing both protein mass and abundance of multiple samples. Applicants' arguments are found unpersuasive for the reasons below.

Chong et al. describes profiling proteins of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS) (Abstract; page 1987, column 1, lines 5-7; and page 1993, Column 1, lines 6-10). Chong et al. teaches: 1) the depiction of protein profile maps side-by-side in Figure 1, wherein the protein samples are separated and are indicative of protein abundance (intensity); and 2) utilizes the Beckman System Gold HPLC which has a programmable solvent delivery module with a dual pump (switchable, multichannel valve), further the System Control Center permits the control of the pump and external modules directly (additionally pumps, therefore, multi-channel valve). This fulfills the definition of "a switchable multi-channel valve" which is as follows:

> "A switchable multi-channel valve allows multiple apparatus to be connected to one automated sample handler." (page 14, lines 8-10 of the Specification)

wherein multiple apparatuses (i.e. modules) are connected to the automated sample handler (i.e. System Control Center). However, Chong et al. fails to indicate the protein abundance can be represented graphically as color intensity bands.

Richmond et al. describes an automated high-throughput flow injection analysis electronspray-mass spectrometry to analyze liquid chromatography fractions, wherein the liquid chromatography fraction data is rendered in color to provide a fast and easy inspection (Abstract). The authors illustrate and describe the methodology of displaying the liquid chromatography data as graduating color bands representing mass and intensity (page 34, beginning on the right column, line 14; Figures 2 and 3).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Chong et al. in view of Richmond protein profiling of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS), with Richmond et al., graphical display of color intensity bands representing (intensity/mass) from liquid chromatography information side-by-side. Again, while it is acknowledged Chong et al. does not suggest the need for an alternate display method it is the motivation found in Richmond which provides the combination of these two references since Richmond states colored computer screen pictures and 3D maps provide quick and easy way of delivering liquid chromatography (HPLC) data to laboratories in traditional synthetic chemistry, combinatorial chemistry and natural products chemistry. With respect to Applicants assertion Richmond et al. teaches away from a combination with Chong et al., particularly the analysis of proteins would not be conducted in laboratories in traditional synthetic chemistry, combinatorial chemistry and

natural products chemistry; is found moot since proteins are known in the art to be chemical compounds that are naturally found or can be synthesized.

The rejection of claims 35-37 under 35 U.S.C. § 103(a) as being unpatentable over Chong et al. taken in view of Richmond et al. further in view of Pandey et al. (Proteomics to study genes and genomes. Nature. 15 June 2000, Volume 405, pages 837-846) is maintained for reasons of record.

Applicants argue Pandey et al. does not teach the element of differential display to depict protein profile maps alone or in combination with Chong and/or Richmond.

Chong et al. taken in view of Richmond et al. is herein applied as above and from the previous office actions. However, Chong et al. and/or Richmond et al. fail to utilize differential display to depict protein profile maps.

Again, Pandey et al. describes the use of differential display in proteomics for comparison of protein levels (Abstract). The process of applying differential display to mass spectrometry data is described and illustrated (pages 838-839, beginning on the left column line 52; pages 841-843, beginning on the left column line 25; Figures 1 and 3). Further, protein profile maps are depicted side-by-side (Figures 1 and 3).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Chong et al., protein profiling of whole cell lysates wherein protein fractions are separated by non-porous reverse phase HPLC and analyzed using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOFMS), with Richmond et al., graphical display of colour intensity bands representing (intensity/mass) from liquid chromatography information side-by-side, further with Pandey et al. differential display of

protein data from mass spectrometry. Since Pandey et al. describes the application of differential display in the field of proteomics, particularly mass spectrometry protein profile maps for a more faster, more convenient, and more comprehensive analysis of protein (pages (841-843, beginning on the left column line 25).

Claims 1-6, 8-24, and 26-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chong et al. taken in view of Richmond et al. further in view of Verentchikov et al. (U.S. Patent Number 6,534,764 B1). Note Verentchikov et al. is applicable as a reference due to its priority document written basis in provisional priority document serial number 60/138,861.

Chong et al. taken in view of Richmond et al. is herein applied as above and from the previous office actions. However, neither reference teaches the specific utilization of electronspray ionization-orthogonal acceleration-time-of-flight mass spectrometry.

Verentchikov et al. describes an improvement in mass spectrometry regarding certain types therein directed to time-of-flight methods and instruments (Abstract). The inventors summarize developments in mass spectrometry and indicate a further need for improvement thereof (Columns 1-5). Verentchikov et al. disclose these improvements in mass spectrometry to include electron spray ionization ion sources (Columns 5-7; Column 7, lines 5-10). Mass spectrometry improvements are detailed wherein a specific type of practice is orthogonal acceleration for mass spectrometry practice (Column 9, lines 63-67). Generic samples are described, however, peptide samples are clearly given a reasonable expectation of success in such practice (Column 17, lines 14-16).

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize electronspray ionization-orthogonal acceleration-time-of-flight mass

spectrometry with the combination of Chong et al. in view of Richmond et al. because of the cited advantages in Verentchikov et al. to result in the practice of the instant invention with a reasonable expectation of success.

DECLARATION UNDER 37 C.F.R. § 1.132

The declaration under 37 C.F.R. § 1.132 filed 23 August 2004 has been considered and entered. However, the declaration is insufficient to overcome the rejection of claims 1-6, 8-24, and 26-34 based upon the cited prior art of Chong et al. (Rapid Screening of Protein Profiles of Human Breast Cancer Cell Lines Using Non-porous Reversed-phase High Performance Liquid Chromatography Separation with Matrix-assisted Laser Desorption/Ionization Time-of-flight Mass Spectral Analysis. Rapid Communications in Mass Spectrometry, 1999, Volume 13, page 1808-1812) taken in view of Richmond et al. (High-throughput flow injection analysis-mass spectrometry with network delivery of colour rendered results: the characterisation of liquid chromatography fractions, Journal of Chromatography. 1999, Volume 835, pages 29-39) further in view of Pandey et al. (Proteomics to study genes and genomes. Nature. 15 June 2000, Volume 405, pages 837-846) as set forth in the previous Office action because:

a. the expert opinion of David M. Lubman in the declaration under 37 C.F.R. § 1.132 is inadequate to overcome the rejection of claims 1-6, 8-24, and 26-34 based upon the cited prior art of Chong et al. in view of Richmond et al. further in view of Pandey et al. because there is no factual evidence supporting the statement. That is the expert opinion by David M. Lubman fails to set forth facts that the cited prior art does not include, for example, 1) a protein profile map where the protein profile map includes a display of each protein in a sample as a separate band coorresponding to the mass of the protein where the intensity of the band corresponds to the

abundance of the protein in the sample; 2) side by side display of proteins; 3) switchable, multichannel valve for use in delivering sample from one apparatus to another as claimed in the instantly claimed method. (See M.P.E.P. § 716.01(c))

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness. Therefore, the declaration under 37 C.F.R. § 1.132 is insufficient to overcome the rejection of claims 1-6, 8-24, and 26-34 based upon the cited prior art of Chong et al. taken in view of Richmond et al. further in view of Pandey et al.

ACTION IS FINAL, AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: CSM

Date: November 12, 2004

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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